DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 13, 2015

DISPO-MED (MALAYSIA) SDN BHD
c/o Mr. Paul Dryden
Regulatory Consultant
21, Jalan Teknologi 3/5A
Pusat Teknologi Sinar Damansara, Kota Damansara
47810 Petaling Jaya, Selangor Darul Ehsan, Malaysia

Re: K143127
Trade/Device Name: Dispo-Med Oxygen Delivery / CO2 Sampling Cannula Style
Dispo-Med Gas Sampling Only Style
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: January 13, 2015
Received: January 14, 2015

Dear Mr. Dryden

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K143127

Device Name

Dispo-Med Oxygen delivery / CO_2 sampling cannula style
Dispo-Med Gas sampling only style

Indications for Use *(Describe)*

The Dispo-Med nasal cannula styles are intended to deliver supplemental oxygen to patients and provide a means to sample expired gases.

The Dispo-Med gas sampling lines are intended to interface with the patient via nasal cannula, nares connector, or standard sampling port connectors to the expired gas monitor.

Environment of use – hospital, sub-acute, and pre-hospital settings

Patient population – Patients requiring supplemental oxygen and / or expired gas monitoring, adult to pediatrics.

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Date Prepared: 12-Feb-2015

DISPO-MED (MALAYSIA) SDN BHD
21, Jalan Teknologi 3/5A
Pusat Teknologi Sinar Damansara, Kota Damansara
47810 Petaling Jaya, Selangor Darul Ehsan, Malaysia

Tel – +603-6730 4966
Fax – +603-6143 6866

Official Contact: NC Leow - CEO

Proprietary or Trade Name: Dispo-Med Oxygen delivery / CO_2 sampling cannula style
Dispo-Med Gas sampling only style

Common/Usual Name: analyzer, gas, carbon-dioxide, gaseous phase (accessories)

Classification Name: analyzer, gas, carbon-dioxide, gaseous phase (accessories)
CCK – CFR 868.1400
Class II

Predicate Devices: O_2/CO_2 style devices
K010024 - Oridion
K011050 – Oridion
CO_2 sampling style devices
K980325 – Oridion
K980325 – Oridion

Device Description:
Dispo-Med has designed a series of exhaled gas sampling devices. They include:

- Nasal cannula styles that can provide supplemental O_2 and sample exhaled gases
- Gas sampling only devices which sample the patient's exhaled gas at the nares or in the circuit

All of the devices have the same indications for use and therefore can be combined into a single submission.

We will present several different configurations which have been tested and compared to several predicates.

Gas sampling devices are not specific to a particular exhaled gas monitor. Almost all gas sampling design connect to the monitor via a standard luer fitting, whether it is a female or male fitting.

Indications for Use:
The Dispo-Med nasal cannula styles are intended to deliver supplemental oxygen to patients and provide a means to sample expired gases.

The Dispo-Med gas sampling lines are intended to interface with the patient via nasal cannula, nares connector, or standard sampling port connectors to the expired gas monitor.

Environment of use – hospital, sub-acute, and pre-hospital settings

Patient population – Patients requiring supplemental oxygen and / or expired gas monitoring, adult to pediatrics.

O_2 delivery / CO_2 sampling Cannula style

Table 1 – Comparison - O_2 delivery / CO_2 sampling Cannula style presents a comparison of the Dispo-Med Oxygen delivery / Gas Sampling cannula style products, which provide supplemental oxygen and samples expired gases like the predicates, K010024 and K011050 – Oridion Nasal cannula sampling products.

The difference between the predicates is only that K011050 has a design which also allows for oral CO_2 sampling, whereas K011024 only samples from the cannula nares. Otherwise the devices have the same indications for use.

Table 1 – Comparison - O_2 delivery / CO_2 sampling Cannula style

Attribute	**Predicates** **Oridion** **K010024 and K011050**	**Proposed** **DM-4000, DM-4441, DSM-6500, and DM-4601**
Indications for Use	K010024 - Oridion To sample exhaled gas via a nasal cannula and simultaneously provide supplemental oxygen near the nose and mouth for inhalation K011050 - Oridion Used whenever the physician needs to measure the CO_2 in a patient's breathing in a non-intubated patient	The Dispo-Med nasal cannula styles are intended to deliver supplemental oxygen to patients and provide a means to sample expired gases.
Environments of use	Hospitals, sub-acute, pre-hospital settings	Hospitals, sub-acute, pre-hospital settings
Prescriptive	Yes	Yes
Patient population	Patient requiring supplemental oxygen and / or sampling of expired gases	Patient requiring supplemental oxygen and / or sampling of expired gases
Multiple sizes	Adult to pediatric	Only one size
Sampling tubing specs	Not provided	ID – 1.10 mm / OD – 2.20 to 3.00 mm Length – 2 m

Attribute	Predicates Oridion K010024 and K011050	Proposed DM-4000, DM-4441, DSM-6500, and DM-4601
Single patient use, disposable	Yes	Yes
Basic components	Channeled / split nasal cannula Oxygen tubing Gas sampling line K011050 Mouth sampling part	Channeled / split nasal cannula Oxygen tubing Gas sampling line DM-4601 Mouth sampling part
Materials	Cannula and tubing - PVC Connectors – Polypropylene, ABS	Cannula and tubing - PVC Connectors – Polypropylene, ABS
Performance testing	Comparison End-tidal CO_2 results and waveform at various settings	Comparison End-tidal CO_2 results and waveform at various settings Resistance to flow Tensile strength of connections Luer fitting testing Age testing - Environmental Mechanical testing

Substantial Equivalence Discussion -

Tables 1 above compares the key features of the proposed Dispo-Med Oxygen delivery / CO_2 sampling cannula style devices with the identified predicates, K010024 and K011050 – Oridion Nasal cannula sampling, and it demonstrates that the proposed devices can be found to be substantially equivalent.

In summary, one can conclude that substantial equivalence is met based upon the following:

Indications for Use –
The indications for use are identical for the proposed device when compared to the predicate – K010024 and K011050 – Oridion Nasal cannula sampling.
Discussion – Each device is indicated for use delivering supplemental oxygen and sampling expired gases.

Technology and construction –
The design, fabrication, shape, size, etc. are equivalent to the predicate – K010024 and K011050 – Oridion Nasal cannula sampling.
Discussion – The design incorporates several styles of split / channeled nasal cannula where oxygen and expired gases are provided through the various ports within the cannula. For the oral / nasal style, there is an extra part which is placed near the mouth to sample expired gases which may be exhaled by the patient.

Environment of Use –
The environments of use are identical to predicate - K010024 and K011050 – Oridion Nasal cannula sampling.
Discussion – The environments of use are not specifically disclosed in the predicate 510(k) Summary, but literature would support the listed environments of use. There are no differences in the requirements of each environment of use which would raise any new safety concerns when compared to the predicate - K010024 and K011050 – Oridion Nasal cannula sampling.

Patient Population –
The patient population of pediatrics to adults is equivalent to the predicate - K010024 and K011050 – Oridion Nasal cannula sampling.
Discussion – The patient populations are equivalent to the predicate - K010024 and K011050 – Oridion Nasal cannula sampling.

Non-Clinical Testing Summary –
We performed comparative testing which evaluated the ability to measure a breath, measure a gas, and breathe waveforms under several simulated breathing conditions.

The tests included:

- Comparative CO_2 sampling and waveform performance at breathing rates (12 bpm and 20 bpm), tidal volumes (300 ml and 500 ml), CO_2 concentrations (1% and 5%), and oxygen flow rates (1 lpm and 5 lpm) if the device included supplemental oxygen delivery.
- Environmental and Age testing
- Mechanical testing (Section 18)
    - Luer Fitting per ISO 594-2
    - Flow
    - Strength of bonds
    - Tensile Strength

The results presented show that the proposed Dispo-Med Oxygen delivery / CO_2 sampling cannula style devices performed equivalent to the predicates. The area of differences occurred when there was a higher flow rate (5 lpm) of oxygen which is known to influence CO_2 washout and can caused lower values, however the performance met the performance specifications.

The differences in comparative performance are not considered clinically significant as the user is looking for breath rate and understands that higher oxygen flow rates may cause $EtCO_2$ washout, reduced values.

In all testing demonstrated that the proposed devices are substantially equivalent to the predicates - K010024 and K011050 – Oridion Nasal cannula sampling.

Materials –
We have performed ISO 10993 testing on the component materials of the proposed device which is considered as Indirect contact and direct (skin) contact with the patient which means the following tests are required if a material certification cannot be provided.

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation

Discussion of Differences –

There are virtually no differences between the proposed devices and the predicate. The performance testing has demonstrated that any slight change is not significant to safety or performance.

Gas Sampling only style

Table 2 – Comparison – Gas Sampling only style presents a comparison of the Dispo-Med Gas Sampling only style products, which provide sample expired gases like the predicates, K980325 and K980327 – Oridion Nasal gas sampling only products.

The difference between the predicates is only that K980325 is designed to sample for non-intubated patients while K980327 may be used with intubated patients. Otherwise the devices have the same intended for use, i.e., sampling expired gases.

Table 2 – Comparison – Gas Sampling only style

Attribute	**Predicates** **Oridion** **K980325 and K980327**	**Proposed** **DM-41000, DM-1000,** **DM-7100, and DM-7700**
Indications for Use	K980325 – Oridion Used whenever the physician needs to measure the CO_2 in a patient's breathing in a non-intubated patient K980325 – Oridion Used whenever the physician needs to measure the CO_2 in a patient's breathing in an intubated patient	The Dispo-Med gas sampling lines are intended to interface with the patient via nasal cannula, nares connector, or standard sampling port connectors to the expired gas monitor.
Environments of use	Hospitals and / or sub-acute	Hospitals and / or sub-acute
Prescriptive	Yes	Yes
Patient population	Patient requiring sampling of expired gases Non-intubated (K980325) and Intubated (K980327)	Patient requiring sampling of expired gases
Multiple sizes	Adult to pediatric	One size

Attribute	Predicates Oridion K980325 and K980327	Proposed DM-41000, DM-1000, DM-7100, and DM-7700
Sampling tubing specs	Not provided	ID – 1.10 mm / OD – 2.20 to 3.00 mm Length – 2 m
Single patient use, disposable	Yes	Yes
Basic components	Connector to sample from the patient Small bore tubing Connects to expired gas monitor	Connector to sample from the patient Nasal cannula, nares connector or sampling port Small bore tubing Connects to expired gas monitor
Materials	Cannula and tubing - PVC Connectors – Polypropylene, ABS	Cannula and tubing - PVC Connectors – Polypropylene, ABS
Performance testing	Comparison End-tidal CO_2 results and waveform at various settings	Comparison End-tidal CO_2 results and waveform at various settings Resistance to flow Tensile strength of connections Luer fitting testing Age testing - Environmental Mechanical testing

Substantial Equivalence Discussion -

Tables 2 above compares the key features of the proposed Dispo-Med CO_2 sampling only style devices with the identified predicates, K980325 and K980327 – Oridion Nasal gas sampling only products, and it demonstrates that the proposed devices can be found to be substantially equivalent.

In summary, one can conclude that substantial equivalence is met based upon the following:

Indications for Use –
The indications for use are identical for the proposed device when compared to the predicate – K980325 and K980327 – Oridion Nasal gas sampling only products.
Discussion – Each device is indicated for use sampling expired gases.

Technology and construction –
The design, fabrication, shape, size, etc. are equivalent to the predicates – K980325 and K980327 – Oridion Nasal gas sampling only products.
Discussion – The design incorporates simple means to interface with the patient or the breathing / ventilator circuit.

Environment of Use –
The environments of use are identical to predicate - K980325 and K980327 – Oridion Nasal gas sampling only products.

Discussion – The environments of use are not specifically disclosed in the predicate 510(k) Summary, but literature would support the listed environments of use. There are no differences in the requirements of each environment of use which would raise any new safety concerns when compared to the predicate - K980325 and K980327 – Oridion Nasal gas sampling only products.

Patient Population –
The patient population of pediatrics to adults is equivalent to the predicate - K980325 and K980327 – Oridion Nasal gas sampling only products.
Discussion – The patient populations are equivalent to the predicate - K980325 and K980327 – Oridion Nasal gas sampling only products.

Non-Clinical Testing Summary –
We performed comparative testing which evaluated the ability to measure a breath, measure a gas, and breathe waveforms under several simulated breathing conditions.

The tests included:

- Comparative CO_2 sampling and waveform performance at breathing rates (12 bpm and 20 bpm), tidal volumes (300 ml and 500 ml), CO_2 concentrations (1% and 5%).
- Environmental and Age testing
- Mechanical testing
    - Luer Fitting per ISO 594-2
    - Flow
    - Strength of bonds
    - Tensile Strength

The results show that the proposed Dispo-Med CO_2 sampling only style devices performed equivalent to the predicates.

The differences in comparative performance related to better performance of the proposed device vs. the predicates.

In all testing demonstrated that the proposed devices are substantially equivalent to the predicates - K980325 and K980327 – Oridion Nasal gas sampling only products.

Materials –
We have performed ISO 10993 testing on the component materials of the proposed device which is considered as Indirect contact and direct (skin) contact with the patient which means the following tests are required if a material certification cannot be provided.

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation

Discussion of Differences –
There are virtually no differences between the proposed devices and the predicate. The performance testing has demonstrated that any slight change is not significant to safety or performance.

Substantial Equivalence Conclusion -
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.